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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 2343-181-64 NATL
INTERNATIONAL APPLICATION NO. PCT/US04/00740	INTERNATIONAL FILING DATE 14 January 2004	PRIORITY DATE CLAIMED 14 January 2003
TITLE OF INVENTION METHODS OF PREPARATION OF LIVE ATTENUATED BACTERIAL VACCINES BY ALTERATION OF DNA ADENINE METHYLASE (DAM) ACTIVITY IN THOSE BACTERIA		
APPLICANT(S) FOR DO/EO/US Mark L. LAWRENCE, et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
Items 11 to 20 below concern document(s) or information included:		
<p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13(ter.2) and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14 and 1.16. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER																																																							
10/541,246		PCT/US04/00740		2343-181-64 NATL																																																							
20. Other items or information: IDS Cover Sheet, Form PTO-1449, Cited Documents (51), Statement of Relevancy, List of Related Cases																																																											
<p>The following fees have been submitted</p> <table border="1"> <tr> <td>21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))</td> <td>\$300</td> <td colspan="2">CALCULATIONS</td> <td colspan="2">PTO USE ONLY</td> </tr> <tr> <td>22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))</td> <td>\$</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">All other situations.....\$200</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td>23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))</td> <td>\$</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IS.....\$400</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> <tr> <td colspan="2">All other situations.....\$500</td> <td colspan="2">\$</td> <td colspan="2">\$</td> </tr> </table>						21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a))	\$300	CALCULATIONS		PTO USE ONLY		22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c))	\$	\$		\$		If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0		\$		\$		All other situations.....\$200		\$		\$		23. <input type="checkbox"/> Search fee (37 CFR 1.492(b))	\$	\$		\$		If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....\$0		\$		\$		Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....\$100		\$		\$		International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IS.....\$400		\$		\$		All other situations.....\$500		\$		\$	
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Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property																																																											
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

a. A check in the amount of \$ _____ to cover the above fees is enclosed.

b. Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
A duplicate copy of this sheet is enclosed.

c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1442A duplicate copy of this sheet is enclosed.

d. Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Patent Group
DLA Piper Rudnick Gray Cary US LLP
1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412



SIGNATURE
Piny Wang
NAME
48.328
REGISTRATION NUMBER

IN RE APPLICATION: Mark L. LAWRENCE, et al.

GROUP ART UNIT:

SERIAL NUMBER: 10/541,246

EXAMINER:

FILED: July 1, 2005

FOR: METHODS OF PREPARATION OF LIVE ATTENUATED BACTERIAL VACCINES BY ALTERATION OF DNA
ADENINE METHYLASE (DAM) ACTIVITY IN THOSE BACTERIAINFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents

PO BOX 1450

ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents are attached, where required, as are either statements of relevancy or any readily available full or partial English translations of any non-English-language documents.

RELATED CASES

- Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- without fee and within three months of the filing date of the application.
- without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- without fee and with the appropriate certification above.
- without fee and with a new CPA application.
- without fee and with a Request for Continued Examination.
- with fee and before the mailing date of any Final Office Action, Notice of Allowance or an action that otherwise closes prosecution (to the knowledge of the undersigned).
- with fee, appropriate certification above, and before payment of the Issue Fee.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,
DLA PIPER RUDNICK GRAY CARY US LLPJames M. Heintz
Registration No. 41,828Ping Wang, M.D.
Registration No. 48,318

1200 Nineteenth Street, N.W.
Washington, DC 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085
0105

0105 REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MN/

DOCKET NO. 2343-181-64 NATL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Mark L. LAWRENCE

ART UNIT:

SERIAL NO.: 10/541,246

EXAMINER:

FILING DATE: January 14, 2004

FOR: METHODS OF PREPARATION OF LIVE ATTENUATED BACTERIAL
VACCINES BY ALTERATION OF DNA ADENINE METHYLASE (DAM)
ACTIVITY IN THOSE BACTERIA

STATEMENT OF RELEVANCY

ASSISTANT COMMISSIONER FOR PATENTS
PO BOX 1450
ALEXANDRIA, VA 22313-1450

SIR:

This Statement of Relevancy is herewith submitted with the concurrently filed Information Disclosure Statement. The below cited German language articles are submitted for consideration in the examination of the above-identified application in which an English language translation of the articles could not be located.

1. Geschwend, et al., *Berl. Munch Tierarztl Wschr*, Vol. 110, (1997).

The above cited article briefly describes that *Pasteurella multocida* and *Pasteurella haemolytica* produce specific proteins in the outer membrane under iron-depleted conditions. *Pasteurella multocida* serovar A expresses these proteins of molecular masses of 76 and 96 kDa as determined by electrophoresis. The analogous serovar D produces a further iron-regulated protein of

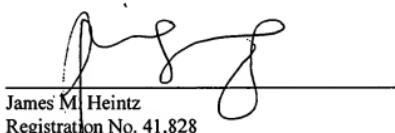
ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /MN/

85 kDa. The *Pasteurella haemolytica* strains of serovar A1, A6 and T contain iron-regulated outer membrane proteins of molecular masses of 71, 77 and 100 kDa. These proteins possess binding positions for iron ions. This article also briefly describes that both *Pasteurella multocida* and *Pasteurella haemolytica* strains utilize iron from porcine and bovine transferrin, but not from haemin and haemoglobin.

Consideration of the above cited references with all Information Disclosure Materials concurrently filed is respectfully requested.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP



James M. Heintz
Registration No. 41,828

Ping Wang
Registration No. 48,328

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085

LIST OF RELATED CASES

Docket Number	Serial or Patent Number	Filing or Issue Date	Status or Patentee
2343-013-27	5,403,863	04-04-06	Granted
2343-179-27	10/767,441	01-30-04	Pending
2343-181-64 NATL	10/541,246	07-01-05	Pending
2343-203 NATL	11/372,187	03-10-06	Pending

The cases listed on this Notice of Related Cases include cases which may contain information that is material to patentability. The listing of a case on this Notice should not be taken as an indication or admission that any information contained therein is material. Prior art for each case listed on this Notice may have been cited. **The files corresponding to the listed cases, which are available to the Examiner, may not have not been examined to ascertain the materiality of any prior art therein.** Accordingly, the Examiner is requested to review the file for each case listed on this Notice in order to assess the materiality of such prior art.

*Present application; listed for information.

Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE	DOCKET NO.	SERIAL NO.
	PATENT AND TRADEMARK OFFICE	2343-181-64 NATL	10/541,246
	APPLICANT		
	Mark L. Lawrence, et al.		
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		FILING DATE	GROUP ART UNIT
		July 1, 2005	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
AA	5,403,863	04-04-95	Mark L. Lawrence, et al.			
AB						
AC						
AD						
AE						
AF						
AG						
AH						
AI						
AJ						

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	NO
AK					
AL					
AM					
AN					
AO					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AP	
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EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH _____/_____/_____. MN/

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LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)		FILING DATE July 1, 2005	GROUP ART UNIT

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

BA	Carter, "Observations on the Pathology and Bacteriology of Shipping Fever in Canada", Can. J. Comp. Med., Vol. 18, No. 10, pp. 359-364, 1954.
BB	Collier, "Significance of Bacteria in Bovine Respiratory Disease", A.V.M.A., Vol. 153, No. 12, pp. 1645-1651, 1968.
BL	Schaefer, et al., "Correlation of Microbiological and Histological Findings in Bovine Fibrinous Pneumonia", Vet. Pathol., Vol. 15, pp. 313-321, 1978.
BD	Purdy, et al., "Serotyping and Enzyme Characterization of <i>Pasteurella haemolytica</i> and <i>Pasteurella multocida</i> Isolates Recovered from Pneumonic Lungs of Stressed Feeder Calves", Current Microbiology, Vol. 34, pp. 244-249, 1997.
BL	Allen, et al., "The Microbial Flora of the Respiratory Tract in Feedlot Calves: Associations between Nasopharyngeal and Bronchoalveolar Lavage Cultures", Can. J. Vet. Res., Vol. 55, pp. 341-346, 1991.
BF	Singer, et al., "Assessment of spatial and temporal clustering of ampicillin- and tetracycline-resistant strains of <i>Pasteurella multocida</i> and <i>P. haemolytica</i> isolated from cattle in California", JAVMA, Vol. 212, No. 7, pp. 1001-1005, 1998.
BG	Gourlay, et al., "Experimental <i>Pasteurella multocida</i> pneumonia in calves", Res. Vet. Sci., Vol. 47, pp. 185-189, 1989.
BH	Bryson, et al., "Observations on outbreaks of respiratory disease in housed calves - (1) Epidemiological, clinical and microbiological findings", Vet. Rec., Vol. 103, pp. 485-489, 1978.
BI	Virtala, et al., "Epidemiologic and pathologic characteristics of respiratory tract disease in dairy heifers during the first three months of life", JAVMA, Vol. 208, No. 12, pp. 2035-2042, 1996.
BJ	Boyce, et al., "The Capsule Is a Virulence Determinant in the Pathogenesis of <i>Pasteurella multocida</i> M1404 (B:2)", Infection and Immunity, Vol. 68, No. 6, pp. 3463-3468, 2000.
BK	Rimler, et al., "Lipopolysaccharides of the Heddleston serotypes of <i>Pasteurella multocida</i> ", Am. J. Vet. Res., Vol. 45, No. 4, pp. 759-763, 1984.
BL	Brogden, et al., "Incubation of <i>Pasteurella haemolytica</i> and <i>Pasteurella multocida</i> lipopolysaccharide with sheep lung surfactant", Am. J. Vet. Res., Vol. 47, No. 4, pp. 727-729, 1986.
BM	Confer, et al., "Intranasal vaccination of rabbits with <i>Pasteurella multocida</i> A:3 outer membranes that express iron-regulated proteins", AJVR, Vol. 62, No. 5, pp. 697-703, 2001.

EXAMINER

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

BN	Geschwend, et al., "Untersuchungen zu den Proteinen der auBeren Membran von Pasteurellen 2. Mittelilung; Eisenregulierte Proteine der auBeren Membran bei <i>Pasteurella multocida</i> und <i>Pasteurella haemolytica</i> ", Berl. Munch Tierarztl Wschr, Vol. 110, p. 386-390, 1997.
BQ	Negrete-Abascal, et al., "Secretion of Proteases from <i>Pasteurella multocida</i> Isolates", Curr. Microbiol., Vol. 38, pp. 64-67, 1999.
BP	Strauss, et al., "In Vivo Production of Neuraminidase by <i>Pasteurella haemolytica</i> in Market Stressed Cattle After Natural Infection", Current Microbiol., Vol. 37, pp. 240-244, 1998.
BQ	White, et al., "Extracellular Neuraminidase Production by a <i>Pasteurella multocida</i> A:3 Strain Associated with Bovine Pneumonia", Infection and Immunity, Vol. 63, No. 5, pp. 1703-1709, 1995.
BQ	Galdiero, et al., "Effects of the major <i>Pasteurella multocida</i> porin on bovine neutrophils", AJVR, Vol. 59, No. 10, pp. 1270-1274, 1998.
BS	Fuller, et al., "Identification of <i>Pasteurella multocida</i> virulence genes in a septicemic mouse model using signature-tagged mutagenesis", Microb. Pathog., Vol. 29, pp. 25-38, 2000.
BT	May, et al., "Complete genomic sequence of <i>Pasteurella multocida</i> , Pm70", Proc. Natl. Acad. Sci. USA, Vol. 98, No. 6, pp. 3460-3465, 2001.
BU	Blyn, et al., "Regulation of <i>pap</i> pilin phase variation by a mechanism involving differential Dam methylation states", The EMBO J., Vol. 9, No. 12, pp. 4045-4054, 1990.
BV	Braaten, et al., "Methylation Patterns in <i>pap</i> Regulatory DNA Control Pyelonephritis-Associated Pili Phase Variation in <i>E. coli</i> ", Cell, Vol. 76, pp. 577-588, 1994.
AW	van der Woude, et al., "Leucine-responsive regulatory protein and deoxyadenosine methylase control the phase variation and expression of the <i>sfa</i> and <i>daa</i> pili operons in <i>Escherichida coli</i> ", Mol. Microbiol., Vol. 11, No. 4, pp. 605-618, 1994.
BX	Henderson, et al., "The Major Phase-Variable Outer Membrane Protein of <i>Escherichia coli</i> Structurally Resembles the Immunoglobulin A1 Protease Class of Exported Protein and Is Regulated by a Novel Mechanism Involving Dam and OxyR", J. of Bacteriol., Vol. 181, No. 7, pp. 2132-2141, 1999.
BY	Heithoff, et al., "An Essential Role for DNA Adenine Methylation in Bacterial Virulence", Science, Vol. 284, pp. 967-970, 1999.
BZ	Julio, et al., "DNA Adenine Methylase Is Essential for Viability and Plays a Role in the Pathogenesis of <i>Yersinia pseudotuberculosis</i> and <i>Vibrio cholerae</i> ", Infect. and Immun., Vol. 69, No. 12, pp. 7610-7615, 2001.

EXAMINER

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OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

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EXAMINER

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